



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0755; FRL-9366-3]

Dinotefuran; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for residues of dinotefuran in or on pome fruits and stone fruits. This action is in response to EPA's granting of emergency exemptions under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on pome fruits and stone fruits. This regulation establishes a maximum permissible level for residues of dinotefuran in or on these commodities. The time-limited tolerances expire on December 31, 2015.

This regulation also makes the systematic chemical name for dinotefuran consistent within the section and with EPA's policy on chemical nomenclature.

DATES: This regulation is effective [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0755, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm.

3334, 1301 Constitution Ave., NW, Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Andrea Conrath, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9356; email address: conrath.andrea@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at

http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under section 408(g) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2012-0755 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2012-0755, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Background and Statutory Findings

EPA, on its own initiative, in accordance with FFDCA sections 408(e) and 408(l)(6), 21 U.S.C. 346a(e) and 346a(1)(6), is establishing time-limited tolerances for combined residues of dinotefuran, (RS)-1-methyl-2-nitro-3-((tetrahydro-3-furanyl)methyl)guanidine, including its metabolites and degradates, in or on pome fruits and stone fruits at 1.0 part per million (ppm). These time-limited tolerances expire on December 31, 2015.

Section 408(l)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on FIFRA section 18 related time-limited tolerances to set binding precedents for the application of

FFDCA section 408 and the safety standard to other tolerances and exemptions. Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, i.e., without having received any petition from an outside party.

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that “emergency conditions exist which require such exemption.” EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

III. Emergency Exemptions for Dinotefuran on Pome Fruits and Stone Fruits and FFDCA Tolerances

Several States requested emergency exemptions claiming that the abrupt increase and spread of damaging populations of the Brown Marmorated Stink Bug (BMSB) resulted in an urgent and non-routine pest control situation. The available insecticides for BMSB control are either ineffective, adversely impact integrated pest management programs, and/or have use limitations that make them unsuitable for season-long control of BMSB. The States asserted that without the use of dinotefuran as an additional pest management tool for pome and stone fruit orchards, uncontrolled infestations of BMSB are likely to result in economic losses in excess of 20%. After having reviewed the submissions, EPA determined that an emergency condition exists for these States, and that the criteria for approval of the emergency exemptions were met. EPA authorized specific exemptions under FIFRA section 18 for the use of dinotefuran on pome fruits and stone fruits for control of the BMSB in Delaware, Maryland, New Jersey, North Carolina, Pennsylvania, Virginia, and West Virginia.

Consistent with the need to move quickly on the emergency exemptions in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing these tolerances without notice and opportunity for public comment as provided in FFDCA section 408(l)(6). Although these time-limited tolerances expire on December 31, 2015, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amounts specified in the tolerances remaining in or on pome fruits and stone fruits after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by these time-limited tolerances at the time of that application. EPA will take action to revoke these time-limited tolerances earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because these time-limited tolerances are being approved under emergency conditions, EPA has not made any decisions about whether dinotefuran meets FIFRA's registration requirements for use on pome fruits and stone fruits or whether permanent tolerances for this use would be appropriate. Under these circumstances, EPA does not believe that these time-limited tolerance decisions serve as a basis for registration of dinotefuran by a State for special local needs under FIFRA section 24(c). Nor do these tolerances by themselves serve as the authority for persons in any State other than Delaware, Maryland, New Jersey, North Carolina, Pennsylvania Virginia, and West Virginia to use this pesticide on the applicable crops under FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemptions for dinotefuran, contact the Agency's

Registration Division at the address provided under **FOR FURTHER INFORMATION CONTACT**.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

As part of its evaluation of the emergency exemption applications, EPA assessed the potential risks presented by residues of dinotefuran in or on pome fruits and stone fruits. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerances under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18.

EPA has evaluated the use of dinotefuran on pome fruits and stone fruits, as well as various other crops, and recently established tolerances for similar use patterns, in the **Federal Register** issue of September 12, 2012 (77 FR 56133) (FRL-9359-6) in

association with requests for tolerances to support registrations of dinotefuran under section 3 of FIFRA.

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for dinotefuran including exposure resulting from the tolerances established by this action.

In the September 12, 2012 **Federal Register** issue, EPA published a final rule establishing tolerances for residues of dinotefuran in 40 CFR 180.603(a) in or on berry, low growing, except strawberry, subgroup 13-07H; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F; onion, bulb, subgroup 3-07A; onion, green, subgroup 3-07B; peach; tea, dried; vegetable, tuberous and corm, subgroup 1C; and watercress. A summary of the toxicological endpoints for dinotefuran used for human risk assessment is discussed in Units III.A. and B. of the September 12, 2012 final rule.

The human health risk assessment used to support the September 12, 2012 final rule (“Dinotefuran: Human Health Risk Assessment for Proposed Section 3 Uses on Tuberous and Corm Vegetables Subgroup 1C, Onion Subgroup 3-07A, Onion Subgroup 3-07B, Small Fruit Subgroup 13-07F, Berry Subgroup 13-07H, Peach, and Watercress, And a Tolerance on Imported Tea”), took into account the assumption that dinotefuran would be used on pome fruits and stone fruits pursuant to emergency exemptions.

Therefore the aggregate risks for dinotefuran for this action are not changed from those discussed in the September 12, 2012 final rule.

In its aggregate assessment of exposures and risks associated with dinotefuran, EPA concluded the following: That the acute dietary exposure from food and water to dinotefuran will occupy 5.8% of the acute population adjusted dose (aPAD) for children 1-2 years old, the population group receiving the greatest exposure; that chronic exposure to dinotefuran from food and water will utilize 2.6% of the chronic population adjusted dose (cPAD) for children 1-2 years old, the population group receiving the greatest exposure; and that the combined short-term risk from food, water, and residential exposures result in an aggregate margin of exposure (MOE) of 3,000 for children 1-2 years old from hand to mouth exposure from treated turf, the scenario with the highest exposure. Because EPA's level of concern for dinotefuran is a MOE of 100 or below, the MOEs are not of concern. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, dinotefuran is not expected to pose a cancer risk to humans.

Therefore, EPA concluded that there is a reasonable certainty that no harm will result to the general population and to infants and children from aggregate exposure to dinotefuran residues. Refer to the September 12, 2012 final rule, available at <http://www.regulations.gov>, for a summary of the aggregate risk assessments and determination of safety. A more detailed discussion of the aggregate risk assessments and determination of safety may be found at <http://www.regulations.gov> in the document titled "Revised: Dinotefuran: Human Health Risk Assessment for Proposed Section 3 Uses on Tuberous and Corm Vegetables Subgroup 1C, Onion Subgroup 3-07A, Onion Subgroup 3-07B, Small Fruit Subgroup 13-07F, Berry Subgroup 13-07H, Peach, and

Watercress, And a Tolerance on Imported Tea’’ in docket ID number EPA-HQ-OPP-2011-0433.

EPA relies upon those risk assessments and the findings made in the **Federal Register** document in support of this action.

V. Other Considerations

A. Analytical Enforcement Methodology

There are several analytical methods available for determination of residues of dinotefuran and its metabolites. For determination of dinotefuran and its metabolites, DN, 1-methyl-3-(tetrahydro-3-furylmethyl)guanidine, and UF, 1-methyl-3-(tetrahydro-3-furylmethyl)urea, a high performance liquid chromatography/tandem mass spectrometry (HPLC/MS/MS) method is available. For the determination of residues of dinotefuran only, an HPLC/ultraviolet (UV) detection method is available. For the determination of only the metabolites (DN and UF), HPLC/MS and HPLC/MS/MS methods are available. These methods are adequate to enforce the tolerance expression.

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and

Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There are currently no Codex, Canadian or Mexican MRLs established for dinotefuran.

VI. Conclusion

Therefore, time-limited tolerances are established for residues of dinotefuran, (RS)-1-methyl-2-nitro-3-((tetrahydro-3-furanyl)methyl)guanidine, including its metabolites and degradates, in or on fruit, pome, group 11 and fruit, stone, group 12 at 1.0 ppm. These tolerances expire on December 31, 2015.

EPA is also revising 40 CFR 180.603(b) to use the same systematic chemical name for dinotefuran as is presently used in 40 CFR 180.603(a), for purposes of consistency within the section and with EPA's policy regarding chemical nomenclature.

VII. Statutory and Executive Order Reviews

This final rule establishes tolerances under FFDCA sections 408(e) and 408(l)(6). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of

Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established in accordance with FFDCA sections 408(e) and 408(l)(6), such as the tolerances in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded

mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 1, 2012.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. In § 180.603, revise paragraph (b) to read as follows:

§ 180.603 Dinotefuran; tolerances for residues.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances are established for residues of dinotefuran, (*RS*)-1-methyl-2-nitro-3-((tetrahydro-3-furanyl)methyl)guanidine, including its metabolites and degradates, in or on the commodities in the following table, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemptions. Compliance with the tolerance levels specified in the table is to be determined by measuring only the sum of dinotefuran and its metabolites DN, 1-methyl-3-(tetrahydro-3-furylmethyl)guanidine, and UF, 1-methyl-3-(tetrahydro-3-furylmethyl)urea, calculated as the stoichiometric equivalent of dinotefuran, in or on the commodities listed in the table. The tolerances expire and are revoked on the dates specified in the table.

Commodity	Parts per million	Expiration/revocation date
Fruit, pome, group 11	1.0	12/31/15
Fruit, stone, group 12	1.0	12/31/15
Rice, grain	2.8	12/31/12

* * * * *

[FR Doc. 2012-27403 Filed 11/08/2012 at 8:45 am; Publication Date: 11/09/2012]